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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1195]

Draft Guidance for Industry on Bioanalytical Methods Validation for Human Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Bioanalytical Methods Validation for Human Studies.'' This draft guidance provides assistance to sponsors and applicants of investigational new drug applications (IND's), new drug applications (NDA's), abbreviated new drug applications (ANDA's), and supplements, in developing validation information for bioanalytical methods used in human clinical pharmacology, bioavailability, and bioequivalence studies. This draft guidance does not cover analytical methods used for nonhuman pharmacology/toxicology studies, chemistry, manufacturing, and controls information, or in vitro dissolution studies.

DATES: Written comments may be submitted on the draft guidance document by (*insert date 60 days after date of publication in* **Federal Register**). General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Submit written requests for single copies of ''Bioanalytical Methods Validation for Human Studies'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing

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your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vinod P. Shah, Center for Drug Evaluation and Research (HFD–350), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5635.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Bioanalytical Methods Validation in Human Studies.'' This draft guidance is based primarily on the report of a conference on Analytical Methods Validation: Bioavailability, Bioequivalence and Pharmacokinetic Studies, held on December 3 to 5, 1990, sponsored by FDA, the American Association of Pharmaceutical Scientists, Federation Internationale Pharmaceutique, the Canadian Health Protection Branch, and Association of Official Analytical Chemists.

This draft level 1 guidance document is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on bioanalytical methods validation in human studies. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, at any time, submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number

found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 24, 1998

William K. Hubbard
Associate Commissioner for Policy Coordination

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